

902 KAR 11:035. Proficiency test procedures.

RELATES TO: KRS Chapter 333

STATUTORY AUTHORITY: KRS 194.050

NECESSITY, FUNCTION, AND CONFORMITY: KRS Chapter 333 authorizes the Cabinet for Human Resources to periodically inspect medical laboratories in Kentucky and to withhold the issuance of a license to the medical laboratory until the cabinet determines that the laboratory is adequately staffed and equipped to operate in conformity with the requirements of KRS Chapter 333 and the administrative regulations promulgated thereunder. KRS Chapter 333 directs the Secretary for Human Resources to adopt rules and regulations to effectuate the purposes of KRS Chapter 333 including the licensure of medical laboratories, standards of performance in the examination of specimens, and the operation by the cabinet of a medical laboratory evaluation program. This administrative regulation describes the proficiency test program which shall be employed by the cabinet to evaluate the work of medical laboratories.

Section 1. Definitions. (1) "Reference laboratory" means a laboratory designated by the cabinet to authenticate the identification, content, or titer of samples and other materials used in proficiency testing.

(2) "Referee laboratory" means a laboratory designated by the cabinet to examine specimens or other materials for proficiency testing using the time schedule allowed for licensed laboratories and under conditions similar to those under which licensed laboratories examine materials.

Section 2. Proficiency Testing; Procedures, Samples, Test Conditions. Applicants and licensees shall be subject to a proficiency testing program approved by the cabinet, to aid in assessing the competency of laboratory staff and the adequacy and quality of facilities, equipment, reagents, working conditions, and procedures. Testing may be carried out during on-site inspections by the cabinet or by submittal to laboratories of samples for examination. In conducting testing, the following rules shall apply:

(1) The laboratory shall be tested only in those procedures or specialties of procedures for which a license application, original or renewal, has been filed with the cabinet, or for which the cabinet has issued a license.

(2) Samples shall be examined by regularly assigned personnel using the laboratory's routine methods.

(3) Samples to be tested may be provided prior to, during, or subsequent to inspections.

(4) Time allowed for testing of samples shall be the time required under conditions of normal laboratory operations, as determined by the cabinet.

(5) Laboratory personnel shall enter the date and time of receipt of samples, results of tests, and other information required by the cabinet, on forms provided or required by the cabinet.

Section 3. Proficiency Testing; Reference Laboratories and Referee Laboratories. Samples identical to those submitted to the applicant or licensee laboratory shall be submitted to reference or referee laboratories designated by the cabinet.

Section 4. Proficiency Testing; Reporting of Test Scores. (1) If laboratory reports reflect a lack of proficiency, the cabinet may recommend corrective measures, consultation, or training in an appropriate laboratory and may, upon written request of the laboratory director, furnish the laboratory with additional samples after corrective measures have been taken.

(2) Results reflecting a lack of proficiency may constitute a basis for denial, revocation, suspension, or limitation of the laboratory license, as provided by KRS 333.190(3). (3 Ky.R. 201; eff. 5-4-

1977; 20 Ky.R. 2184; eff. 3-14-1994; Crt eff. 3-22-2019.)